

**DOCKET NO.:** CARP-0123/P035760US/HGH  
**Application No.:** 10/579,981  
**Office Action Dated:** September 14, 2007

**PATENT**

### REMARKS

Following entry of the foregoing amendments, claims 1 to 3, 10, 11, 13 to 41, 44, 45, and 72 will be pending in this patent application. Claims 1, 10, 11, 36, and 37 have been amended and claims 12, 46 to 71, and 73 have been canceled, herein, without prejudice. No new claims have been added.

Applicant respectfully requests reconsideration of the requirements for restriction and election of species in view of the following remarks.

#### Restriction Requirement

The Office requires applicant to restrict the claimed subject matter to one of five groups of inventions under 35 U.S.C. §§ 121 and 372. The claims of each group, and the subject matter said to be associated with each group, are set forth in the table below.

Group	Claims	Subject Matter
I	1 to 11, 13 to 37, and 41	A transformed host cell comprising a chromosomal gene that inhibits cell growth and a plasmid encoding an antisense sequence.
II	12 and 46 to 71	A host cell comprising a chromosomal gene that inhibits cell growth.
III	38 to 40	Methods of maintaining a plasmid in a host cell <i>in vitro</i> and isolating plasmid DNA or protein from the cell.
IV	44, 72, and 73	Methods of delivering a gene to a patient and immunizing a patient comprising administering a transformed host cell to the patient.
V	45	Methods of maintaining a plasmid in a recipient organism.

The Office asserts that the inventions of groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical

feature that defines a contribution over the prior art. Applicant respectfully traverses the restriction requirement because the entirety of the subject matter recited in the present claims is, in fact, so linked as to form a single general inventive concept that defines a contribution over the prior art.

Preliminarily, applicant notes that claim 1 has been amended herein to recite transformed host cells comprising a chromosomal gene that inhibits cell growth that is operably linked to a regulatory sequence. Claim 1 has also been amended to recite that the cells further comprise a plasmid comprising an origin of replication that encodes an antisense sequence that binds to mRNA transcribed from the regulatory sequence, and binding of the antisense sequence encoded by the origin of replication of the plasmid to mRNA transcribed from the regulatory sequence inhibits the action of the chromosomal gene, thereby permitting cell growth. Support for the amendments is found throughout the specification as originally filed, including, for example, page 5, lines 8 to 9 and 21 to 23 and page 3, lines 10 to 11. The amendments thus do not introduce new matter into the application. Claims 12, 46 to 71, and 73 have been canceled herein.

The relationship among the subject matter recited in the claims as amended herein is such that it involves one or more of the same or corresponding special technical features that are patentably distinct from the prior art. For example, all of the currently pending claims recite the technical feature of an antisense sequence encoded by the origin of replication of a plasmid that inhibits expression of a chromosomal gene by binding to mRNA transcribed from a regulatory sequence operably linked to the chromosomal gene. Moreover, this technical feature of the antisense sequence and its mechanism of inhibiting gene expression defines a contribution over the prior art. Although the Office asserts that this is not the case because Shohat, *at al.*, *Oncogene*, 1987, 1, 227-283 (“the Shohat article”) describes “anti-sense RNA to p53,”<sup>1</sup> the Shohat article does not describe or suggest the claimed antisense sequence and its mechanism of inhibiting gene expression. Rather, the Shohat article describes transfection of cells with plasmids encoding antisense mRNA molecules that inhibit the expression of the p53 protein.

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<sup>1</sup> Office action dated September 14, 2007, page 2.

The article does not describe or suggest, however, an antisense sequence encoded by the origin of replication of a plasmid. In addition, the article does not describe or suggest an antisense sequence that inhibits expression of a chromosomal gene by binding to mRNA transcribed from a regulatory sequence operably linked to the chromosomal gene. Accordingly, the claimed antisense sequence and its mechanism of inhibiting gene expression recited in the present claims defines a contribution over the prior art.

The entirety of the subject matter recited in the present claims thus relates to a single general inventive concept that defines a contribution over the prior art, and restriction of the claimed subject matter is therefore improper. Nevertheless, in accordance with 37 C.F.R. § 1.499, applicant hereby provisionally elects the subject matter of group I for prosecution on the merits, directed to transformed host cells comprising a chromosomal gene that inhibits cell growth operably linked to a regulatory sequence and a plasmid comprising an origin of replication encoding an antisense sequence that binds to mRNA transcribed from the regulatory sequence. The elected subject matter encompasses claims 1 to 11, 13 to 37, and 41.

### **Election of Species Requirement**

The Office also requires a species election. Applicant's undersigned representative contacted the examiner via telephone for clarification of how to respond to the species election since it was not apparent based upon the description provided in the official action. The examiner indicated that applicant is required to elect one of the following host cells: *E. coli*, *Salmonella*, *Bacillus*, fungi, plant, or animal. The examiner further indicated that applicant is also required to elect a chromosomal gene encoding either a toxin, a repressor protein, or an antisense sequence. If applicant elects a chromosomal gene encoding a repressor protein, the examiner indicated, applicant is further required to elect either *lacI*, *dapD*, or *fabA*. In accordance with 37 CFR § 1.146, applicant hereby elects *E. coli* host cells with traverse; applicant further elects a chromosomal gene encoding a repressor protein with traverse; and applicant elects the *lacI* gene, which encodes a repressor protein, with traverse. Applicant notes that the *dapD* and *fabA* genes do not encode repressor proteins, but, rather, encode proteins

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required for cell wall synthesis and fatty acid biosynthesis, respectively. Claims 1 to 3, 10, 11, 13 to 17, 20, 27 to 29, 36 to 41, 44, 45, and 72 read on the elected species.

Applicant traverses the species election on the grounds that the recited species relate to a single general inventive concept that defines a contribution over the prior art for the reasons discussed above in connection with the response to the restriction requirement. It is applicant's understanding that this election is being made solely to aid the examiner in conducting an initial search and examination of the claimed subject matter, and is not to be construed as limiting the scope of applicant's claims. It is applicant's further understanding that, if the elected species is found to be allowable over the prior art, the search and examination will be expanded to cover additional species, until the examination includes the full scope of the subject matter elected in response to the restriction requirement.

## **Conclusion**

Applicant believes that the foregoing constitutes a complete and full response to the official action of record. An early and favorable action is accordingly, respectfully requested.

Respectfully submitted,

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